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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,852	09/22/2000	Per Johan Lundberg	15652-00020-US	1116

30678 7590 08/02/2010

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EXAMINER	
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ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
08/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/646,852	LUNDBERG ET AL.	
	Examiner	Art Unit	
	S. TRAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7-10,12-18,20 and 23-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7-10,12-18,20 and 27-31* is/are rejected.

7)☒ Claim(s) *23-26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 23-26 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 102

Claims 1, 3-5, 7-10, 13, 16, 17, 20, 27 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Lundberg et al. WO 96/24338 A1.

Lundberg teaches an oral dosage form comprising: 1) a core that contains a proton pump inhibitor (PPI), one or more alkaline reacting compounds, and optionally pharmaceutical excipients; and 2) an enteric coating layer (abstract; page 19, lines 10-30; and examples). PPI includes omeprazole, it's salts, or it's enantiomer (claims 9-10). Pharmaceutical excipients include filler, binder, lubricant, surfactant, disintegrant, and other additives (page 12, lines 24-31). Example 3 discloses the use of sodium starch glycolate (swelling agent) as one of the excipients. Alkaline reacting compounds include arginine, and alkali metal phosphate (page 10, lines 20-25). The core comprises starter seed such as sugar sphere (page 12, lines 15-22). Core can be in the form of tablet or pellet (page 9, lines 30 through page 10, lines 1-2; and page 13, lines 4-15). Enteric coating layer comprises a single polymer such as cellulose acetate

phthalate, cellulose acetate succinate, or carboxymethylcellulose (page 11, lines 18-24). Enteric coating layer further comprises talc (examples).

It is noted that Lundberg teaches a separating layer between the core and the enteric coating layer. However, while the present claims recite that the core material is not coated with a separating layer, the claims do not preclude the coating of the swelling agent(s) as a layer between the active core and the semipermeable membrane. This is evident by the limitations recited in claims 6 and 20. Example 2 in the present specification further clarify the layers on the core include the swelling layer containing L-HPC. This layer is coated onto the PPI containing core before the semipermeable membrane. Moreover, the separating layer taught by Lundberg is formed by an in situ reaction between the enteric coating polymer and the alkaline core. The burden is shifted to the Applicant to show that the alkalizing additives and the semipermeable membrane of the present invention do not form an in situ separating layer. This is because the claimed dosage form utilizes the same alkaline reacting compound and the same polymer for the semipermeable membrane.

It is also noted that Lundberg does not teach that alkaline additives give a pH of not less than 8.5 when measured in a 2% w/w water solution/dispersion with a pH-measuring electrode. However, such property is inherent because Lundberg teaches the use of the same alkaline additives.

Claim Rejections - 35 USC § 103

Claims 1, 3, 7, 8, 12-18, 20 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nara et al. US 6,245,351, in view of Bergstrand et al. US 5,753,265.

Nara teaches a controlled release composition comprising a drug-containing core coated with a protective coating layer containing hydrophilic substances (column 6, lines 1-10). Hydrophilic substances include hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methylcellulose, polyvinylpyrrolidone, and polyvinyl alcohol (column 5, lines 1-4). The amount of this protective coating is about 1 to about 15% to the core (ID). Drugs include omeprazole and lansoprazole (column 3, lines 59-60). The drug is mixed with excipient, such as sucrose or calcium phosphate (osmotic agent); binder; disintegrant, such as, sodium crosslinked carboxymethylcellulose or low-substitutional hydroxypropyl cellulose (swelling agent); and lubricant, including talc (alkaline additive) (column 5, lines 36-52; and examples). The core can be in the form of a granule, fine granule, or inert carrier particles including sucrose (column 5, lines 30-35, and 60-65). The coated core can be prepared in tablet or capsule form for oral administration (column 6, lines 56-65; and claim 7).

Nara does not explicitly teach the addition of a modifying agent in the protective coating composition.

Bergstrand teaches an omeprazole core is coated with a separating layer (protective coating layer) comprising polymer such as ethylcellulose, hydroxypropyl methylcellulose, polyvinylpyrrolidone, methylcellulose, and polyvinyl alcohol (column 7,

lines 51-61). Bergstrand further teaches the polymer can be used alone (as a single polymer) (column 7, line 62). The separating layer further comprises plasticizer, and antistatic agents such as talc (column 7, lines 63-65; and examples 1, 3 and 7). Thus, it would have been obvious to one of ordinary skill in the art to modify the protective coating composition of Nara to include additives such as talc in view of the teaching of Bergstrand to obtain the claimed invention, because Bergstrand teaches adding talc to the coating composition to increase the thickness of the layer and thereby strengthen the diffusion barrier, because Bergstrand teaches the separating layer improves the chemical stability of the active substance and the physical properties of the dosage form (column 8, lines 21-27), because Nara teaches the desirability of using a separating layer to protect the acid sensitive active core, and because Nara teaches the use of other agent to help modify the coating properties (modifying agent) (example 11, lines 49-50).

Regarding the limitation "water-insoluble polymer capable of forming a semipermeable membrane", it is noted that Nara and Bergstrand teach the use of the claimed water-insoluble polymers. Therefore, the burden is shifted to applicant to show that the water-insoluble polymers taught by Nara and Bergstrand do not have the claimed property. This is because identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nara et al. US 6,245,351, in view of Bergstrand et al. US 5,753,265 and Hodges et al. US 5,225,202.

Nara is relied upon for the reason stated above. Nara does not explicitly teach the amount of alkaline additive present in the core.

Hodges teaches a controlled release pellet comprising acid labile drug in the core, and one or more buffering agents (alkaline additives) (see abstract, and column 3, lines 1-4; lines 15-19). Buffering agents present in the core in an amount ranging from about 1 to about 20% (column 3, lines 34-36). Thus, it would have been obvious to one of ordinary skill in the art to use alkaline additive in an amount taught by Hodges to obtain a stable acid labile composition, because Hodges teaches using buffering agent in an amount of about 1 to about 20% to aid in minimizing drug degradation in the core due to acid ingress in low pH environments (column 3, lines 6-9), and because Nara teaches a composition with low toxicity and can be safely used in mammals.

It is noted that Nara does not explicitly teach the weight ratio of the modifying agent to water-insoluble substance, as well as the amount of the alkaline additive and swelling agent in the core. However, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, it would have been obvious to one of ordinary skill in the

art to, by routine experimentation determine suitable amount of talc in the core composition as well as in the coating composition, because Nara teaches the release rate of the active ingredient is mainly in the small and large intestine without an enteric coating, while the release rate of the active ingredient is very limited in the stomach (column 1, lines 53-55; and column 7, lines 25-31), and because Nara teaches a coated formulation with low toxicity that can be safely used in human. The expected result would be a controlled-release composition comprising omeprazole in the core without enteric coating that can limit release of omeprazole in the stomach, but increases release in the small and large intestine.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nara et al. US 6,245,351, in view of Bergstrand et al. and, Zentner US 4,795,644 or Lundberg et al. 6,013,281.

Nara is relied upon for the reasons stated above. Nara is silent of the claimed alkaline agent.

Zentner teaches pH-modifying agent includes sodium mono- or di-phosphate (column 8, lines 3-15).

Lundberg teaches alkaline reacting compound includes arginine (column 6, lines 50-55). Thus, it would have been obvious to one of ordinary skill in the art to modify the compositions of Nara using sodium mono- or di-phosphate and arginine compound as an alkaline agent, because the references teach suitable composition for the same

active agent, namely, omeprazole, and because Nara teaches the desirability of using an alkaline agent in the composition.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nara et al. US 6,245,351, in view of Bergstrand et al., and Cotton et al. WO 98/54171.

Nara is relied upon for the reasons stated above. Nara is deficient in the fact that Nara does not specifically teach magnesium salt of omeprazole.

Cotton teaches novel form of S-enantiomer of omeprazole, including S-omeprazole, and more specifically, magnesium salt of S-omeprazole trihydrate (hereafter, the compound) (see abstract, and page 1, lines 4-10). Cotton also teaches the compound is formulated into oral dosage form, *e.g.*, capsule, tablet, and the like (page 6, lines 15-30). The formulation is effective as a gastric acid secretion inhibitor and is useful as an anti-ulcer agent (page 6, lines 1-14).

Cotton does not explicitly teaches the compound having a crystallinity of more than 70%, however, Cotton teaches that the compound of his invention is highly crystalline, *i.e.*, having a higher crystallinity than any other form of magnesium salt of S-omeprazole in the prior art (page 3, lines 24 through page 4, lines 1-7). Therefore, the burden is shifted to applicant to show the compound taught by Cotton does not have the crystallinity being claimed. It is also noted that Cotton teaches the trihydrate form, *e.g.*, magnesium salt of S-omeprazole "trihydrate". However, applicant claims recite a generic form of magnesium salt of S-omeprazole with the transitional phrase "comprising of" permits any other form, including "trihydrate" taught by Cotton. Thus, it

would have been obvious for one of ordinary skill in the art to modify the controlled release composition comprising a drug-containing core coated with a *non-enteric* coating composition using the magnesium salt of S-omeprazole trihydrate in view of the teaching of Cotton, because Cotton teaches the compound of his invention is more stable, easier to handle and store, easier to synthesize in a reproducible manner, because Cotton teaches the compound is most preferred in oral administration formulation, because Nara teaches a non-enteric coated formulation with low toxicity that can be safely used in human. The expected result would be a controlled-release composition comprising omeprazole in the core without enteric coating that can limit release of omeprazole in the stomach, but increases release in the small and large intestine.

Response to Arguments

Applicant's arguments filed 05/17/10 have been fully considered but they are not persuasive.

Applicant argues that the 102(b) rejection by Lundberg is improper because the dosage forms of Lundberg *et al.* have an enteric coating and a separating layer, both of which are excluded by the claims. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California,* 814 F.2d 628, 631 (Fed. Cir. 1987). Lundberg *et al.* describes coating an alkaline core material with an enteric coating and forming a separating layer between the core and the enteric coating

in situ. See, e.g., Lundberg *et al.*, column 5, lines 51-58. During the interview of April 29, 2010, the examiner explained that Lundberg *et al.* might anticipate the claims if the "enteric coating" of Lundberg *et al.* is identical to the semipermeable membrane of the instant claims. In other words, if the "enteric coating" of Lundberg *et al.* and the "semipermeable membrane" of the instant claims are made-up of the same materials it is of no consequence that they are called different names. In response to the Examiner's concerns, Applicants' representative pointed out that even if the "enteric coating" of Lundberg *et al.* were somehow interpreted to be the semipermeable membrane according to the instant claims, the dosage forms of Lundberg *et al.* still cannot anticipate the claims because they include a separating layer formed *in situ* (the instant claims exclude a separating layer). Accordingly, the rejection is improper and should be withdrawn.

However, in response to Applicant's arguments that *Lundberg teaches the separating layer which was excluded by the present claims*, the Examiner notes that the separating layer in Lundberg is formed by *in situ*. In other words, the core material of Lundberg is not prepared or made with the core being physically coated with a separating layer. The present claims require that "the core material is not coated with a separating layer". Similarly, Lundberg teaches a PPI core is directly coated with an enteric coating layer (page 9, lines 31 through page 10, lines 1-5; and page 13, lines 20-25). All of the examples in Lundberg further disclose that the active core is directly coated with an enteric coating layer. Further, it is noted that the present invention is made similar to that of Lundberg, in which there is a separating layer forming in situ.

See for example the disclosure at page 4, lines 10-22; page 7, lines 16-20; and Figures 3-4. Accordingly, the present claims do not preclude the separating layer forming *in situ* by the reaction between the alkalizing agent in the core and the polymer coating layer.

Applicant argues that Nara *et al.,* the primary reference relied upon in the rejection, describes a core material coated with a polymer composition containing two or three polymers, *i.e.,* a water insoluble polymer, a swellable polymer, and an optional hydrophilic substance (which includes certain polymers). *See* column 6, lines 16-21, claims 1 and 9, and Examples 1-11. Nara *et al.* also describes a separating layer in column 6, lines 1-10. In the section entitled "Response to Arguments" on page 10 of the Office Action, it states that applicants' claims do not exclude a separating layer comprising a single polymer composition. *See* Office Action dated December 15, 2010, page 10, lines 13-16. It is not clear to applicants how the examiner is construing the claims to include a separating layer even though the claims explicitly recite that "the core material is not coated with a separating layer." Because the references do not account for a core material coated with a semipermeable membrane comprising a single polymer composition without a separating layer, the rejection is improper and should be withdrawn. The rejection is further improper because the references actually teach away from coating a core material with a semipermeable membrane comprising a single polymer composition without a separating layer. Where a reference teaches away from and discourages a person skilled in the art from doing what is claimed, the

reference establishes "the very antithesis of obviousness." *In re Buehler* 185 USPQ 781 (CCPA 1975).

In response to Applicant's arguments with respect to the separating layer, however, it is of note that the present specification does not specific define the term "separating layer" to provide adequate direction of the specific location of such "separating layer" in the dosage form. As such, the claims must be given their broadest reasonable interpretation. According to the teaching of Nara, the core is coated with a protecting layer, and then the coating composition comprising water-insoluble polymer (columns 5-6). The protecting layer comprises a single polymer such as a hydrophilic substance (column 6, lines 1-10). The protecting layer is directly coated onto the core without any separating layer. See column 6, lines 1-3. Accordingly, the protecting layer taught in Nara reads on the semipermeable membrane of the present claims. The water insoluble coating composition on top of the protecting layer is not precluded by the present claims.

Applicant argues that Nara *et al.* is the primary reference of the rejection. It lists examples of drugs that may be employed in a controlled-release composition in column 3, lines 34-64. Omeprazole is one of many alternative compounds in this enormous list of diverse drug substances. Moreover, omeprazole is not exemplified in any examples or otherwise indicated as preferred (it is mentioned only once). Nara *et al.* repeatedly exemplifies morphine hydrochloride and phenylpropanolamine hydrochloride, not omeprazole. A prior art reference that teaches or suggests a preferred embodiment

different from the claimed subject matter weighs against a determination of obviousness. *In re Baird,* 16 F.3d 380, 82-83, (Fed. Cir. 1994); *see also* MPEP 2144.08(II)(A)(4). Assuming one would select omeprazole from the enormous list in Nara *et al.* (even though Nara *et al.* does not exemplify or otherwise indicate that omeprazole is preferred), the reference teaches that the core material should be coated with a composition comprising multiple polymers. *See, e.g.,* the abstract and the examples. Nara *et al.* describes a core material coated with a composition comprising a water insoluble polymer, a swellable polymer, and an optional hydrophilic substance (which can be a polymer). Additionally, Nara *et al.* teaches the use of a protective layer. *See* column 6, lines 1-10 and 16-21, claims 1 and 9, and Examples 1-11. Thus, Nara *et al.* specifically teaches away from proceeding as applicants have done by requiring the use of a coating comprising multiple polymers and by encouraging the use of a protective layer.

In response to Applicant's arguments with respect to the coating layers, however, as discussed above, the protecting layer taught in Nara reads over the claimed semipermeable membrane. The present claims do not preclude the present of the water insoluble coating composition taught in Nara.

In response to Applicant's arguments that Nara does not teach omeprazole in the examples, it is noted that the use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain. *In re*

Heck, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)).

Applicant argues that the Office Action cites Bergstrand *et al.* (US 5,753,265) as applicable to claims 9-10 and 30-31. Bergstrand *et al.* explains that H+K+-ATPase inhibitors such as omeprazole "are best protected from contact with acidic gastric juice by an enteric coating layer." *See* column 4, lines 5-7 (emphasis added). It goes on to describe a separating layer in column 7, lines 43-50. Thus, Bergstrand *et al.* teaches away from proceeding as applicants have done by indicating the need for an enteric coating and a separating layer.

In response to applicant's arguments, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Bergstrand is cited solely for the teachings that using pharmaceutically acceptable excipients such as talc in a coating composition is known in the art.

The Office Action cites Hodges *et al.* (US 5,225,202) as applicable to claims 30-31. Hodges *et al.* is directed to an enteric coated pharmaceutical composition for a medicament that is sensitive to a low pH environment. *See* the abstract. It describes

using a "subcoat layer" to act as a physical barrier between the core and outer enteric coating layer in column 4, lines 59-65. Thus, Hodges *et al.* teaches away from proceeding as applicants have done by indicating the need for an enteric coating and a separating layer. The art of record explicitly teaches the need to coat omeprazole with a composition comprising multiple polymers and/or an enteric coating. The art of record also explicitly teaches the need for a separating layer. In the instant case, applicants proceeded contrary to the teachings of the art and developed a dosage form that does not include an enteric coating or a separating layer.

In response to applicant's arguments, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Hodges is relied upon solely for the teachings of the use of buffering agents present in the core in an amount ranging from about 1 to about 20% (column 3, lines 34-36).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615